

Message

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Subject: News Update: Advocates Fault EPA Review Finding Glyphosate Unlikely To Cause Cancer (Inside EPA)

RISK POLICY REPORT - 05/10/2016

Advocates Fault EPA Review Finding Glyphosate Unlikely To Cause Cancer

May 09, 2016

Environmentalists are faulting an EPA assessment finding the world's most commonly-used herbicide is not likely to cause human cancers, arguing the agency relied on industry studies and unrealistic assumptions.

They also say the agency appears to lack confidence in its own review, given that EPA posted the document to a public site and then withdrew it days later.

EPA April 29 posted its Oct. 1 final report, "Cancer Assessment Document: Evaluation of the Carcinogenic Potential of Glyphosate" finding the substance is unlikely to cause cancer but then withdrew that document along with a dozen others May 2. *Relevant documents are available on InsideEPA.com. (Doc. ID: 191011)*

"Preliminary glyphosate documents were inadvertently posted to the agency's docket. These documents have now been taken down because EPA's assessment is not final," an EPA spokeswoman tells *Inside EPA*.

The Center for Biological Diversity (CBD) is arguing that the EPA review is flawed, and that the agency's decision to pull the six-month old document from a public website appears to back CBD's claims.

"We shouldn't gamble with the risk of cancer and must take appropriate precautions until we get a conclusive answer about the true dangers of glyphosate," CBD says in a May 2 statement.

In the Oct. 1 review, EPA's pesticides office's Cancer Assessment Review Committee (CARC) weighs human and animal data and determines that glyphosate is "Not Likely to be Carcinogenic to Humans."

EPA's review also faults a World Health Organization International Agency for Research on Cancer (IARC) March 2015 report that concluded glyphosate probably causes cancer, saying IARC overlooked negative findings, which could have influenced that group's findings.

EPA is currently conducting a required Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registration review of glyphosate, which is commonly used with genetically-modified (GM) crops, but the agency says it re-evaluated the substance's potential cancer risk given the IARC finding and new data.

"EPA has not completed our cancer review," the EPA spokeswoman says. "We will look at the work of other governments as well as work by [the Department of Health and Human Services'] Agricultural Health Study as we move to make a decision on glyphosate. Our assessment will be peer reviewed and completed by end of 2016."

Environmentalists have longed called for stronger EPA oversight of glyphosate, arguing widespread use of the substance on GM crops is depleting habitat for monarch butterflies and spurring weed resistance, leading farmers to spray more herbicides, including reverting to older more toxic substances.

Last year IARC in a March 20 monograph classified glyphosate "probably carcinogenic" to humans, prompting advocates to broaden their opposition to the substance's heavy use.

But a second report spurred industry arguments that glyphosate is safe. The European Food Safety Authority (EFSA) Nov. 12 peer review calls glyphosate "unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential."

EFSA said at the time that the primary reason for IARC's differing conclusion was because IARC considered both glyphosate and products containing the substance, while EFSA reviewed only the active ingredient.

The IARC review drew criticism from House Republicans, and EPA toxics chief Jim Jones said during a May 2015 hearing of the House Agriculture biotechnology, horticulture and research subcommittee that the agency expected to release draft risk reviews of glyphosate in 2015, though the documents have yet to be released.

Jones also said that EPA was considering a broader pool of studies than IARC did.

In the Oct. 1 final report, EPA's says it tasked the CARC to review glyphosate's cancer risk after the IARC report, and that the IARC review considered two studies that EPA did not have when it previously considered glyphosate's potential to cause cancer in the 1980s and 90s. Those reviews did not conclude glyphosate is a carcinogen.

EPA's CARC weighed epidemiological, or human data, as well as toxicity studies in rats and mice. CARC finds that the epidemiological data shows no association between glyphosate exposure and numerous cancers, and found there is conflicting evidence for an association between glyphosate exposure and non-Hodgkin's lymphoma.

The group also concludes there is no evidence of carcinogenicity in rats and mice, and says that "[t]here is no convincing evidence that glyphosate induces micronuclei formation or chromosomal aberrations in vitro or in vivo."

While ultimately classifying glyphosate as "Not Likely to be Carcinogenic to Humans," EPA faults IARC's March 2015 review, arguing IARC included studies with analytical and design flaws, omitted studies with negative results, and considered studies that tested glyphosate-formulated products where the tested material was not well characterized.

"The inclusion of the positive findings from studies with known limitations, the lack of reproducible positive findings and the omission of the negative findings from reliable studies may have had a significant bearing on IARC's conclusion," EPA says.

A source with CBD tells *Inside EPA* that EPA's finding that glyphosate is unlikely to cause cancer is a "major roadblock" for advocates' calls for significant new restrictions on the substance, noting that a positive carcinogenicity finding would have led to additional reviews and analysis.

The source also argues that EPA will struggle to defend its analysis, which considered industry-funded studies, some of which have not been publicly released. The source also says EPA discounted studies that failed to show a dose relationship between exposure and effect, which the source says reflects an outdated risk assessment paradigm, given that certain substances are known to cause effects at low doses.

The source also says EPA's handling of the six-month old document likely reflects both political pressure on the agency, and possibly a lack confidence in their own findings.

"It makes me think that EPA is very nervous about this decision," the source says. "They're going to have a hard time defending this document in the public eye."

Other documents that EPA publicly posted April 29 and withdrew May 2 include a presentation from Monsanto, a producer of glyphosate-based herbicides, to EPA, guidance for considering toxicity studies in human health risk assessment, and a preliminary ecological risk assessment supporting EPA's registration review of the substance. -- *Dave Reynolds*

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